

What is claimed is:

1. A substantially purified p100 which is a human neu related protein having a molecular weight in the range from about 97,000 daltons to about 115,000 daltons which corresponds substantially to the extracellular domain of the human neu gene product, said protein being detectable in a biological fluid.
2. A protein according to claim 1 wherein the protein is capable of being detected in an immunoblot format by a monoclonal antibody which is capable of binding p100.
3. A method of detecting preneoplastic or neoplastic cells in a human which comprises testing a biological fluid from the human for the presence of p100 by:
  - (a) contacting the fluid with at least one monoclonal antibody which is capable of binding p100; and
  - (b) determining whether antibody binding has occurred.
4. A method according to claim 3 wherein the cancer is ovarian, breast, stomach, pancreatic, colon or lung cancer.
5. A method according to claim 3 wherein the biological fluid is selected from the group consisting of blood, serum, plasma, urine, cerebrospinal fluid, supernatant from normal cell lysate, supernatant from preneoplastic cell lysate, supernatant from neoplastic cell lysate, and breast aspirates.
6. An immunoassay for detecting or quantifying the presence of p100 in a biological fluid obtained from a human which comprises

49

- (a) reacting the fluid with at least one first monoclonal antibody which is capable of binding to p100;
- 5 (b) reacting the product of step (a) with at least one detectably-labeled second monoclonal antibody which is capable of binding to p100 at an epitope different from the epitope bound by the first antibody; and
- 10 (c) detecting or quantifying the product of step (b).

7. An assay according to claim 6 wherein immunoreactive fragments are used.

15 8. An assay according to claim 6 wherein the detectable label is selected from the group consisting of radioisotopes, enzymes, fluorogenic, chemiluminescent and electrochemical materials.

20 9. An assay according to claim 6 wherein the second antibody is conjugated to biotin.

25 10. An assay according to claim 9 wherein the biotin-conjugated antibody is detected by reacting the biotinylated complex first with streptavidin-horseradish peroxidase followed by reaction with orthophenylenediamine.

30 11. An assay according to claim 6 wherein the first antibody is selected from the group consisting of antibodies produced by the hybridoma cell lines having ATCC accession numbers HB 10205 and HB 10206.

12. An assay according to claim 6 wherein the second antibody is selected from the group consisting of

antibodies produced by the hybridoma cell lines having ATCC accession numbers HB 10205 and HB 10206.

13. A monoclonal antibody which is capable of  
5 binding to p100 which is a human neu related protein  
having a molecular weight in the range from about 97,000  
daltons to about 115,000 daltons wherein said protein  
corresponds substantially to the extracellular domain of  
the human neu gene product, said protein being  
10 detectable in a biological fluid.

14. An immunoreactive fragment of the  
antibody of claim 13.

15. A hybridoma cell line producing the  
antibody of claim 13.

Sub  
B1  
20

16. Hybridoma cell line having ATCC accession  
number HB 10204.

17. Hybridoma cell line having ATCC accession  
number HB 10205.

18. Hybridoma cell line having ATCC accession  
25 number HB 10206.

add  
B27

add D1